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09/367,712	08/18/99	SEFTON J	17224 (AP)

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HM12/0308

EXAMINER

BADIO, B.

ART UNIT	PAPER NUMBER
1616	12

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UNITED STATES DEPARTMENT OF COMMERCE  
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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 09/367,712  
Filing Date: August 18, 1999  
Appellant(s): John Sefton

Paper No. 12  
*mailed out*  
*date - 3-8-01*

Cynthia H. O'Donohue  
For Appellant

**EXAMINER'S ANSWER**

This is in response to appellant's brief on appeal filed January 12, 2001.

**(1) *Real Party in Interest***

The brief does not contain a statement identifying the Real Party in Interest.

Therefore, it is presumed that the party named in the caption of the brief is the Real Party in Interest, i.e., the owner at the time the brief was filed. The Board, however, may exercise its discretion to require an explicit statement as to the Real Party in Interest.

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**(2) *Related Appeals and Interferences***

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

**(3) *Status of Claims***

The statement of the status of the claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

This appeal involves claims 1-3, 5-8 and 10-13. Claims 4 and 9 have been canceled.

**(4) *Status of Amendments After Final***

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) *Summary of Invention***

The summary of invention contained in the brief is correct.

**(6) *Issues***

The appellant's statement of the issues in the brief is correct.

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**(7) Grouping of Claims**

Appellant's brief includes a statement that claims 1-3, 5-8 and 10-13 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

**(8) Claims Appealed**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(9) Prior Art of Record**

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

4,775,529	SEQUEIRA et al.	10-1988
5,236,906	YAMAMOTO	8-1993
5,650,279	NAGPAL et al.	7-1997
5,874,074	SMITH	2-1999

**(10) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

- a) Claims 1-3, 5-8 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto ('906) and Nagpal et al. ('279) in combination.

Yamamoto teaches it is known in the art to use adrenocortical hormones, such as fluocinolone acetonide, betamethasone valerate and clobetasol propionate, in the treatment of skin diseases such as psoriasis and atopic dermatitis (col. 1, line 11 - col. 2, line 55).

Nagpal et al. teach it is known in the art to use tazarotene in the treatment of psoriasis (col. 1, lines 42-47).

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The instant claims differ from the cited references by reciting the combined use of a corticosteroid and tazarotene in the treatment of skin diseases such as psoriasis. However, it is known in the art as indicated above to use each of the recited compound in the treatment of psoriasis. The combination of two compounds/compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose would have been obvious to one having ordinary skill in the art. In re Kerkhoven, 205 USPQ 1069 (CCPA 1980). Thus, the claimed composition is prima facie obvious based on the combined teachings of the above references. The ordinary artisan would be motivated to use combination treatment for a number of reasons including the reduction of the adverse effect of each of the compound utilized.

Claims 3, 7 and 8 further differ from by reciting specific pharmaceutical formulation containing 0.1% tazarotene.

However, the preparation of various formulation containing various amounts of the active ingredients for topical use is within the level of skill of one having ordinary skill in the pharmaceutical art and, thus, is within the level of skill of the ordinary artisan. In addition, finding the optimum amount of the active ingredient useful in the treatment of said disorder is also within the level of skill of the ordinary artisan and it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

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b) Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith ('074) or Sequeira et al. ('529) in combination with Nagpal et al. ('279).

Both Smith and Sequeira et al. teach the use of corticosteroids, such as alclometasone dipropionate and betamethasone dipropionate in the treatment of psoriasis (see '074, col. 4, lines 47-67; '529, col. 1, lines 36-63).

Nagpal et al. teach it is known in the art to use tazarotene in the treatment of psoriasis (col. 1, lines 42-47).

The instant claims differ from the cited references by reciting the combined use of a corticosteroid and tazarotene in the treatment of skin diseases such as psoriasis. However, it is known in the art as indicated above to use each of the recited compound in the treatment of psoriasis. The combination of two compounds/compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose would have been obvious to one having ordinary skill in the art. In re Kerkhoven, 205 USPQ 1069 (CCPA 1980). Thus, the claimed composition is prima facie obvious based on the combined teachings of the above references. The ordinary artisan would be motivated to use combination treatment for a number of reasons including the reduction of the adverse effect of each of the compound utilized.

**(11) Response to Argument**

Applicant argues that the cited prior art do not provide motivation to combine tazarotene and a mid- or high-potency corticosteroid in the treatment of psoriasis as presently

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claimed. Applicant also argues that mid- or high-potency corticosteroids in combination with tazarotene exhibit a synergistic effect that provides a more effective treatment of psoriasis than either agent alone or with low-potency corticosteroid. Applicant's argument was considered but not persuasive for the following reasons.

Each of the compounds recited by the claimed invention is known in the art to be useful in the treatment of psoriasis as evidenced by the cited prior art. Combination therapy is well known in the art and is done regularly in the medical art. In addition, the courts have held that the combination of two compounds/compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose is *prima facie* obvious. In re Kerkhoven, 205 USPQ 1069 (CCPA 1980). Thus, the combination of tazarotene with a corticosteroid (i.e., mid- or high- potency) for the treatment of psoriasis would have been obvious to one having ordinary skill in the art at the time of the present invention. The motivation to make the combination is based on the fact that each is known to be useful for the treatment of psoriasis as well as the fact that combination therapy is well known in the art. In the medical art, the prime reasons for combination therapy is to reduce the adverse effect caused by one or both agents utilized and/or to provide a more effective treatment by using a combination of two agent useful for said disorder.

Applicant argues that mid- or high-potency corticosteroids in combination with tazarotene exhibit a synergistic effect providing a more effective treatment of psoriasis. The effectiveness of each combination is not the prime issue because the ordinary artisan can

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determine by routine experimentation which combination of corticosteroid and tazarotene would provide the most effective treatment and/or have the least adverse effect. The issue is whether the prior art makes obvious to the ordinary artisan the claimed combination and its use in treating psoriasis. The examiner's position is that the cited prior art makes obvious the use of tazarotene and corticosteroids in the treatment of psoriasis because (1) each is taught by the prior art to be useful in treating psoriasis and (2) combination therapy is well known in the medical art.

In summary, the use of tazarotene in combination with a corticosteroid (mid- or high-potency) is prima facie obvious based on the fact that each is known in the art to be useful for treatment of psoriasis.

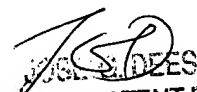
For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

BB  
March 6, 2001

  
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